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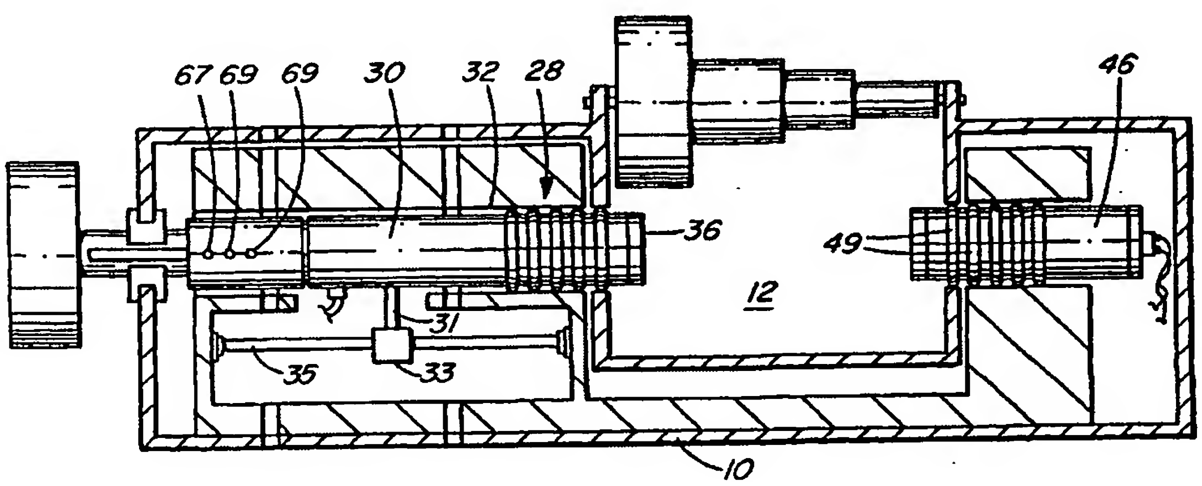

(57) Abstract

An apparatus for measuring physical characteristics comprises means (20) to determine when an object (14) to be tested is correctly placed in the recess (12) of a main body (10). In a preferred embodiment the object is a foot and the device is useful in determining the presence of osteoporosis. Ultrasonic transmitter (34) is resiliently mounted in a first container (30) slidably received in the main body (10). The transmitter (34) is urged towards the object (14) but its movement is restricted. A piezoelectric ultrasonic receiver (48) spaced from the transmitter (34) also projects towards the body (14). The ultrasonic receiver (48) is resiliently mounted in a second hollow container (52) slidably received in the main body (10). The object (14) is subjected to a first frequency obtained by resonating the transmitter (34) in the thickness mode and a second lower frequency obtained by resonance in the radial mode.

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ULTRASONIC SCANNING APPARATUS

FIELD OF THE INVENTION

This invention relates to an apparatus and to a method to measure the physical characteristics of an object. The apparatus and method find particular application measuring the physical characteristics of bone and is thus of value in diagnosing osteoporosis and osteomalacia. However the invention finds general application in assessing the structural properties of materials and in detecting minute changes in that structure. Although this is of particular value in determining the integrity of heterogenous materials such as bone, the invention, in both aspects, is of wider application.

BACKGROUND OF THE INVENTION

Osteoporosis is a condition, more common amongst women than men, characterized by deterioration of the bone. The bone becomes porous and brittle. Osteoporosis at present is diagnosed by measuring the density and elasticity of the bone. High density alone does not determine the bone resistance to fracture. The bone can possess quite high density but still be brittle and therefore susceptible to breakage. Prior art methods of measuring bone density do not have the required degree of accuracy to determine small changes in bone density, which is what is needed to establish optimum therapeutic or diagnostic procedures.

Osteomalacia is a condition in which softening of the bone occurs. Softening is the result of absorption of calcium from the bones. It occurs especially in pregnant women and it is believed to be related to a dietary deficiency in vitamin D.

My co-pending United States Patent Application Serial No. 018,709 filed February 17, 1993 describes and

claims an apparatus to measure the physical characteristic of an object. The apparatus has a bath to receive the object and the object can be stabilized in the bath. Liquid is supplied to and from the bath. The temperature of the liquid can be controlled so that it is above the temperature of the object. An ultrasonic transmitter sends a signal through the object and an ultrasonic receiver receives the signal. The velocity of the signal of the object can be calculated. This apparatus is useful in diagnosing osteoporosis.

The heel bone is suited to ultrasonic measurement with its sides relatively parallel. The heel bone is composed mainly of trabecular bone. The elasticity and strength of this bone is provided by its sheet structure. The manner in which trabeculae are assembled is more significant than the volume or any other characteristic of bone. Rigidity and strength is more a matter of geometry than mass. The trabeculae arrangement, and the contiguity that it provides, is a more important parameter than volume or weight for action of hard tissue in determining the stiffness of trabecular bone. Because of these facts the known methods of utilizing the velocity of sound in bone and the attenuation measurements, although appearing to provide sound theoretical methods, have not been satisfactory in diagnosing osteoporosis and are not capable of evaluating the effectiveness of any treatment procedure.

Another difficulty with existing methods is their dependence upon references or standards. Using the standards creates an additive error to any measurement. In addition to this error, the use of standards having homogenous composition is undesirable as these compositions relate poorly to human bone; human bone is a heterogenous material.

X-ray methods have been used to diagnose osteoporosis but have also been found unsatisfactory. They measure only the density and provide no quantitative evaluation of structure. Because they produce ionizing radiation, X-rays are not suitable for this purpose.

No prior art has shown an ability to measure bone structure, density and the velocity of sound in bone using a single device. The use of a single device provides a means of early detection as well as a more accurate assessment of the degree of osteoporosis.

All the present methods depend highly on instrument electronic stability. This can be undesirable. There can also be a lack of uniformity in the transducer characteristic, stemming from the manufacturing process.

Furthermore the accuracy with which the heel can be re-positioned for repeat measurements is not particularly satisfactory in the prior art. The reapplying of the transducer against the heel with the same conditions, particularly the same contact pressure, for subsequent measurements is also not well done in the prior art.

SUMMARY OF THE INVENTION

The present invention seeks to avoid the disadvantages in the prior art. In particular the present invention allows for instrumental base line drift without the introduction of errors into the measurement. The invention also provides for extremely accurate location of the heel and easy repetition of the location of the heel for subsequent measurements.

A particular advantage of the present invention is that it is self-calibrating.

Accordingly, in its apparatus aspect, the present invention provides an apparatus to measure the physical characteristic of an object comprising:

a main body to receive the object;

means to determine when the object is correctly on the body;

a piezoelectric ultrasonic transmitter to send a signal through the object, said transmitter comprising a first hollow container that is slidably received in the main body and a ceramic transmitter resiliently mounted in said first container;

means urging said transmitter towards said object;

means to restrict the movement of said transmitter;

a piezoelectric ultrasonic receiver spaced from said transmitter and also projecting towards said body, said receiver comprising a second hollow container slidably received in said main body, and a ceramic transducer resiliently mounted in said second hollow container;

means to generate a signal to be transmitted; and

means to amplify said received signal.

In one embodiment the main body includes a recess that receives the object. The means urging the transmitter towards the object then act to urge the transmitter into the recess in the main body.

Preferably the object is a foot.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is illustrated in the drawings in which:

Figure 1 is a plan view of an apparatus according to the present invention;

Figure 1a is a detail of Figure 1;

Figure 2 is a side elevation of the apparatus of Figure 1;

Figures 3a and 3b are further details of Figures 1 and 2;

Figure 4a is a detail of an ultrasonic transmitter useful with the apparatus of the present invention;

Figure 4b is a detail view of an ultrasonic receiver for use with the apparatus of the present invention;

Figure 5 shows schematically the apparatus for the present invention;

Figure 6 illustrates the computer and control circuitry with signal transmission and processing; and

Figures 7a, 7b and 7c are general views;

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The drawings show an apparatus to measure the physical characteristics of an object. As shown particularly in Figures 1 and 2 the apparatus has a main body 10 that includes a recess 12 to receive the object 14, typically a foot as shown in Figure 1a. The apparatus includes means to determine when the object is correctly positioned in the recess. In the illustrated embodiment that means comprises a plurality of pressure sensors. There is a pressure receptor 16 to contact the heel, as shown in Figure 1a, and a pair of pressure sensors 18 to contact under the heel, again as shown in Figure 1a. The operation of these sensors is discussed subsequently, notably with regard to Figure 5.

In addition the apparatus of Figure 1 includes a toe stabilizer 20 also useful to determine the correct position of the object in the recess when the object is a foot 14. The toe stabilizer 20 is stepped and is received in that part of the recess 12 remote from the pressure sensors 16 and 18 for the heel of the foot. As shown particularly in Figure 1a the big toe of the user

is placed against the toe stabilizer and the position thus achieved. It should be noted that the stabilizer is removably attached in the recess which means it can be used for either the left or the right foot. To facilitate removal stabilizer 20 includes a spring loaded mounting 22 shown in Figure 1.

There is a reservoir 24, having a filling cap 26, to hold liquid to be used in the recess 12 during measurement. In this regard, however, it should be emphasized that the use of a fluid and, indeed, the use of a recess 12 to receive the fluid is not essential to the apparatus of the present invention. A virtue of the equipment, at least compared with applicant's own prior art, is that the fluid reservoir 24, the recess 12, and the heating of the fluid are not necessary in the apparatus of the present invention. A viscous liquid or gel may be interposed between the heel and the transducer. Other applications may necessitate the total immersion of the object to be measured, for example if the object has irregular surfaces.

The apparatus of the present invention as illustrated includes heating means 25 (see Figure 5) to ensure that the liquid contained in the reservoir 24, and thus in the recess 12 during measurement, can be maintained at a temperature slightly above the temperature of the object being assessed. This prevents the formation of bubbles in liquids like water, which interfere with the reflecting ultrasound. Temperature is measured by a sensor 27.

There is a piezoelectric ultrasonic transmitter 28 to send a signal through the object 14. As shown particularly in Figures 3a, 3b and 4a the ultrasonic transmitter 28 comprises a first, hollow container 30 that is slidably received in a recess 32 in the main body

10. There is a ceramic transmitter 34, shown in Figure 4, attached to a face plate 36 of the container 30. The container 32 includes connections 38 that extend to a pulse amplifier discussed below.

In addition the container 32 includes O-rings 40 located on its exterior to seal and also to facilitate movement of the container 32 within the main body 10. At its trailing end there is a stud 42 that allows attachment of the container 32 to a spring chamber 44, shown in Figure 3b.

The apparatus also includes a piezoelectric ultrasonic receiver 46, shown particularly in Figure 3a and 4b, and spaced from the transmitter 28 across the recess 12. Like the container 30 of the transmitter 28 the receiver 46 also has O-rings 49 on its outer surface. The ultrasonic receiver 46 including transducer 48 mounted on an end plate 50 of a cylinder 52. O-rings 49 are around the exterior of the cylinder 52 and there is a preamplifier 54, attached to a micro processor through connection 56. There is also an insulating spacer 58 within the second cylinder 52.

Container 30 has a bolt 31 extending from it. A quill 33 is attached to bolt 31 and moves along an optical ruler 35. This is used to determine the position of the container 30 and thus of the transmitter 28.

In both the transmitter and the receiver, the face plates 36 and 50 are desirably resilient and the piezoelectric ultrasonic receiver and transmitter 34 and 48 are ceramic transducers, resiliently mounted. In a preferred embodiment the face plates 36 and 50 are of an adhesive sealant which functions as a resilient seal for the cylinder 32 and 52 and also acts as a supporting structure for the piezoelectric ceramics. In a preferred

embodiment the face plates 36 and 50 also act as focusing devices for the equipment.

The ultrasonic transmitter 28 is urged into the recess 12 in the main body 10 by the provision of spring chamber 44 shown in Figure 3b and including an internal spring 60. Spring chamber 44 has a threaded opening 62 that receives the stud 42 shown in Figure 4. The spring 60 abuts an end 62 of the third chamber 44 and a piston 64, mounted on a rod 66 that extends out of the third chamber 44. The piston acts to compress the spring 60. There are means to fix the position of the piston 64 and thus the tension of the spring 60 in the form of screws 67 that are received in holes 69 as best shown in Figure 3a. In an alternative arrangement illustrated in Figure 3b, there is collar 65 mounted in the main body 10, and provided with engagement means, typically in the form of a recess 68. There are projections or engaging gears 70 on the rod 66 able to engage with the recess 68 in the collar 65. The rod 66 also has a handle 72 to allow rotation.

Using this equipment the rod 66 may be pushed inwardly, until the appropriate tension is achieved in the spring 60 and then rotated so that the engagement means 65 and 68 engage each other to fix the position of the piston 64 and thus the tension in the spring 60.

The tension of the spring 60 can be pre-set by the use of screws 74 that can be located through passageways 76 to be screwed inwardly to compress a nylon bearing 78 into channels 80 provided in the cylinder 44.

Figure 5 shows the control of the equipment. There is a microprocessor 82 that receives signals from the pressure sensors 16 and 18 and acts to control filling and empty of the recess 12 through ports 84 and the

temperature of the fluid in the recess. There is an alternating current supply 86 and an on/off relay 88 controlling the equipment.

The microprocessor 82 will ensure that the recess 12 is filled and emptied, using a pump 90 and the motorized valve 94 shown in Figures 5, according to a pre-set plan. The microprocessor 82 will ensure that the recess 12 will not be filled with liquid, usually water, at an undesirable temperature and will also ensure that the recess 12 is filled and drained as appropriate. It will also ensure that readings cannot be taken unless the heel is properly located. This is done by scanning the signals from the pressure sensors 16 and 18.

Information from the quill 33 is also stored in microprocessor 82.

Figure 6 illustrates the control circuitry. The microprocessor 82 generates a digital representation of the desired transmit waveform into a transmit FiFo (first in first out) memory 96. The microprocessor 82 sets the gain of transmit digital/analog (D/A) and the gain at a receiver pre-amplifier 98. The microprocessor initiates wave form transmission from transmit Fifo 96 through the video D/A power amplifier 100 and the transmit transducer 28. Sound energy from the transmitter 28, having passed through the heel of foot-14, is detected by the receiving transducer 46 and the signal is amplified by the programmable gain pre-amplifier 98 digitized by the video A/D converter 102 and stored in the receiver FiFo memory 104. The microprocessor 82 then retrieves the received waveform from the receiver FiFo memory 104 and performs an analysis. The microprocessor 82 then sends the receive waveform for analysis to a personal computer 106 for storage and display.

To operate the equipment of the present invention as illustrated in the drawings, the microprocessor is programmed to automatically control the temperature, to fill up the empty bath, to record patient names and other data. All of this information is controlled as shown in Figure 6. This is shown schematically as this software is well known.

The reservoir 24 is filled and the temperature in the reservoir raised sufficiently to yield a temperature at several degrees higher in the recess than the temperature of the object, typically a foot. The patient's foot is cleansed with detergent, rinsed and thoroughly dried. A small amount of a wetting agent is added to the reservoir. The heel is then placed in the bath 12 so that specified pressure is exerted against the back and sole part of the heel and this information relayed to the microprocessor by the pressure sensors 16 and 18. If the sole pressures, measured by the sole sensor 18 shown in Figure 5, are unequal the knee is moved to the left or right to achieve equal pressure. This aligns the heel bone perpendicular to the transducers. The knee is maintained in the same position for the duration of the test.

Knob 72 with the off position showing vertically, is pushed until the preset contact pressure against the heel is achieved. The knob 72 is then rotated until the on position is vertical, that is to say the rod 66 is locked within the collar. This enables the retainer screws to hold the spring 60 in a compressed position. The receiver piezoelectric element and associated mechanical mounting allow the receiver to vibrate freely with a minimum of energy lost to the casing. In this configuration the transducers exhibit two strong resonant frequencies, 171,400 Hz and 668,400 Hz. The predominant receiver frequency is the former 171,400 Hz. The effect

of these freely resonating frequencies is that when the receiver is impacted with a small amount of ultrasonic energy, or at the end of receiving a large amount of ultrasonic energy, the receiver exhibits a strong tendency to vibrate 171,400 Hz. The strength of this tendency is directly dependent upon a constant which is the modulus of elasticity of the ceramic material. Thus the material does not need calibration or reference standard. These receiver characteristics and resonant frequencies are used to advantage in determining bone integrity in the following way.

If the transmitter produces, say, two cycles (sinusoidal) of ultrasound at 668,400 Hz the receiver will begin vibrating at 668,400 Hz and then transition to vibrating at 171,400 Hz will take place until the vibrations end. The energy expended by the receiver vibrating at 668,400 Hz versus the energy vibrating at 171,400 Hz depends on the amplitude of the received ultrasound which, in turn, depends on the energy absorbed by the heel. When the signal arrives at the receiver the microprocessor performs a predetermined gain adjustment on the programmable gain preamplifier according to the scheme of Figure 6. This produces a trace of sufficient magnitude for accurate analysis. As the amplitude of the trace for analysis is thus increased or decreased to a predetermined amplitude, it can be said that it is independent of the density or thickness of the heel bone. Therefore it is known that as humans age they lose density. However the loss of structure is a serious event that could lead to fracture. Thus in this method good bone quality could have the same value at 65 as at 25 years of age, unlike bone density, which decreases with age.

A useful measure of bone integrity has been achieved by spectral analysis of the above received waveform

between 80 KHz and 245 KHz, the low frequency and between 245 KHz and 860 KHz for the high frequency component and forming a % ratio according to the formula:

$$\text{T-index} = \left[\frac{\text{Area of High Frequency Component}}{\text{Area of Entire trace}} \times 100\right] - 100 = \%.$$

This equation yields a new type of index, termed the trabecular or t-index of osteoporosis that is easily interpreted. In general a t-index value of 80% to 90% represents healthy bone. Decreasing values below 80% correlate with increasing structural problems. Values as low as 30% have been found in bone having structural problems leading to fracture. As the structural integrity is measured this test can differentiate between osteomalacia and osteoporosis as the integrity of the structure is affected in the latter but not in the former.

An alternative method according to the present invention eliminates the need for spectral analysis. According to this alternative method the transmitter produces, say, a 2 cycle Sinewave burst of ultrasound at 668,400 Hz and the trace is recorded. A second trace of a single cycle is generated at 171,400 Hz and the amplitude adjusted so that the received waveform is the same amplitude as the original waveform. Now the two waveforms can be matched in time so that a minimum difference waveform is obtained. The area of the difference of the waveform is the high frequency component in the ratio above and the area of the second waveform is a total area of the same ratio. This method eliminates the complex spectral analysis and attains a higher lever of accuracy.

In addition to providing a structured integrated value, the apparatus of the present invention can measure bone density and the velocity of sound in bone. Although the density and velocity do not detect the initial stages

of osteoporosis they do provide an indication of how advanced the disease is. Unlike the trabecular (structural) index measurement, the density and velocity measurements require a heel width measurement. The quill 33 shown in the drawings records the horizontal movement of the transmitting transducer 28. The quill 33 is zeroed by inserting a known width gauge between the transducers 28 and 46. This width is inserted into the program and added to subsequent measurements by the quill 33.

The rationale for measuring bone density is as follows:

It has been observed that the low frequency wave (say 171400Hz) passes through the heel bone with very little difference in attenuation from person to person. Whereas a much higher frequency wave (say 668,400Hz) shows large attenuation differences from person to person. These observations enable a self-calibrating method for measuring bone density as follows. A number of measurements are performed on a single individual preferably a healthy male. These measurements consist of recording the voltages necessary to transmit at a low frequency (171,400 Hz) and obtain 180 units of amplitude on the recorder. The lowest value obtained represents optimum coupling between the transducers and the heel. This voltage value is inserted into the program and is referred to as the <u>low frequency normalization factor</u> (L.F.N.F.) and used in the density measurements for <u>all</u> patients.

In operation the heel is maintained in position and the voltages needed to achieve 180 units at the recorder for the low and high frequency pulse (171,400 Hz) are increased or decreased by the microprocessor and the calculation of density computed as follows:

$$\text{Density} = \frac{\underline{\text{L.F.N.F. Amplitude (volt)}}}{\text{Low Frequency Amplitude (volts)}} \times \frac{\underline{\text{High Frequency Amplitude (volt)}}}{\text{Heel Width (mm)}}$$

Density = Volts/Millimetre (Units)

$$\text{Density} = \text{\% of normal young adult value} = \frac{\text{Patient Value}}{\text{Normal Young Adult Value}} \times 100$$

The present device measures bone density more accurately than previous devices because no phantom (reference standard) is needed. Further the degree of coupling between the test object and the transducers is not a source of error as the L.F.N.F. makes a correction for this.

The position of the foot is maintained for the velocity measurement. By recording the time interval for the pulse to travel through the heel and dividing the heel width by this time the velocity is determined in meters/second. The high frequency trace (668,400 Hz) is used to note the time of arrival of the pulse. This is difficult for the computer to detect as the beginning of the trace is ill-defined. The trace is amplified by the preamplifier enabling the beginning of the trace to be detected by the human eye. The computer easily measures the time of second crossing of the base line as displayed on a monitor. That time interval is measured and has been found to be relatively constant for all patients at 2.026 microseconds. As the computer can easily detect the second crossing of the baseline of the trace used for analysis the above constant value of 2.026 is subtracted from the value to provide the precise time of arrival of the pulse. Other than this unique feature of ensuring that the time is measured with extreme accuracy, the velocity method and its use in evaluating bone is well documented and will not be further elaborated on.

Unlike any other device, this method provides the measurement of three parameters of bone quality, namely structural integrity, bone density and velocity of sound

in bone. This enables early detection of osteoporosis and evaluates the therapeutic procedures to correct the condition.

Although the invention describes particularly the use of the method and apparatus to diagnose osteoporosis the apparatus and method can be directly applied to process control in the process industries - food, pulp and paper, petrochemical, pharmaceutical, paint, dairy etc.

Examples - Pulp and Paper Industry - The "t-index" above may be used to indicate the amount of water in the pulp when flowing or in a fixed sample (See Fig. 7). The higher the pulp to water ratio the higher will be the "t-index".

Example - Solids content in the Food Industry - The higher the particulate in a liquid the higher the "t-index".

Example - Density Measurements - The value of density measurements throughout industry is well documented. However, the ultrasonic methods used are not as accurate as the method of the present invention.

In other applications, a higher intensity of sound may be needed. In this case the transducer face plate of adhesive sealant is shaped to achieve the desired focusing of the sound beam as shown in Fig. 7. If the higher intensity is insufficient the receiving and transmitting transducers may be brought closer together by rotating them clockwise, assuming the body of the transducer has a right hand thread. In all applications two resonating frequencies are utilized - a higher and a lower frequency achieved by having piezoelectric ceramics

operating in the thickness and radial mode and mounted so as to minimize the damping.

Although the above method and apparatus are described particularly in relation to diagnosis of osteoporosis it can also be used to distinguish between osteomalacia and osteoporosis and can also be directly applied to process control in industry, for example in the food, pulp and paper, petro chemical, pharmaceutical, paint and dairy industries. Assuming the application is pulp and paper, one application in this industry is to determine the amount of water in a slurry of pulp. The higher the pulp to water ratio the higher will be the index as discussed above. Both the spectral analysis and the different curve will provide the information.

Apparatus to enable the determination of this is shown in Figure 7 where a simple container 110 is installed in a pipeline 112 in which a transmitter 114 and a receiver 116 are mounted on threaded, sealed member. The necessary signals are taken and interpreted as shown in Figure 6. The relevant equipment is not shown in Figure 7. Here is a particular example of the face plates acting as focusing members and to that end they are provided with concave recesses 122.

In other applications a high intensity of sound may be needed. In this case a transducer face plate is shaped to achieve the desired focusing of the sound, as shown in Figure 7b. If the high intensity is not attained the receiving and transmitting transducers may be brought closer together by rotating them clockwise on the threads. The resonating frequencies are always used - and a higher and a lower frequency by having the ceramics operate in the thickness and radial mode respectively.

This aspect of the invention is of extreme importance. For efficient transfer of power from the generator to the medium the two must be acoustically matched. The specific impedance of the ceramic is approximately 30 mRayls and that of water is 1.5 mRayls, there is a need to smooth out the discontinuity so that the transfer of energy from the transducers to the medium is maximized. A layer of a material with an acoustics impedance intermediate between the ceramic and water, by being interposed between the two, provides good matching using polymers with impedances of about 3.5 mRayls. These are readably available. The velocity of sound in these are approximately 2400 metres per second so the thickness required will vary with the frequency used.

Both transducers are air backed. The transmitter is made of a material of 5400 Navy (U.S.A.) whereas the receiver is 5500 Navy (U.S.A.). The diameters of both on 0.5 inches and the thicknesses of both are 0.1 inches. The main body of the transducers should have an outside diameter of about 1 inch and an inner diameter of about 0.6 inches. As the ceramic is only 0.5 inches compression of the ceramic between the body and the object to be measured is prevented. It is only the face plate that is compressed between the object and the main body. The characteristic of the sealant is such that it possesses strong adhesion and remains pliable and is a non-conductor of electrical current. A preferred material for this use is that available under the trademark E 6000 from Eclectic Products, which is a styrene based adhesive sealant. The combined effect of the sealant and the transducer ceramic geometry, that is 5 to 1 ratio of diameter to thickness, disc shape and ceramic mounting techniques allow both transducers to resonate in both the radial and thickness modes. This provides a low resonating frequency in the radial mode

and a high resonating frequency in the thickness mode of vibration. This method of mounting ceramic and using a compliant or resilient face plate not only produces a highly efficient transducer but enables production of piezoelectric transducers that have virtually the same characteristics. The geometry of the transducers is such that the radial mode is preferred. That is if a single burst of energy, of the higher resonating frequency is received by the receiver it will start vibrating at this higher frequency, in the thickness mode and change into the radial mode, proportional to the energy of the burst received. That is to say the length of time spent in the thickness mode is proportional to the energy of the burst received. This competition between radial and thickness modes of vibration is based upon the modulus of elasticity of the ceramic and provides its own reference as the modulus of elasticity is a constant, thus avoiding the necessity for calibration.

Although the present invention has been described in some detail by way of example for purposes of clarity and understanding, it will be apparent that certain changes and modifications may be practised within the scope of the appended claims.

WE CLAIM:

1. Apparatus to measure the physical characteristic of an object comprising:

a main body to receive the object;

means to determine when the object is correctly on the body;

a piezoelectric ultrasonic transmitter to send a signal through the object, said transmitter comprising a first hollow container that is slidably received in the main body and a piezoelectric ceramic transmitter resiliently mounted in said first container, said transmitter having a diameter about 5 times greater than its thickness;

means urging said transmitter towards said object;

means to restrict the movement of said transmitter;

a piezoelectric ultrasonic receiver spaced from said transmitter and also projecting towards said body, said receiver comprising a second hollow container slidably received in said main body, and a ceramic transducer resiliently mounted in said second hollow container, said transducer having a diameter above 5 times greater than its thickness;

means to generate a signal to be transmitted; and

means to amplify said received signal.

2. Apparatus as claimed in claim 1 in which the object is a foot.

3. Apparatus as claimed in claim 1 in which the means to determine when the object is correctly positioned comprises:

a first pressure sensor to contact the under side of the object; and

a second pressure sensor to contact the rear of the object; and

means to generate a signal when pressure is correctly applied to the first and second sensors.

4. Apparatus as claimed in claim 3 in which there are two first sensors.

5. Apparatus as claimed in claim 3 in which, when the object is a foot, the means to determine when the object is correctly positioned includes a toe stabilizer mounted in said recess to abut a side of the toe to ensure the foot is in the correct position.

6. Apparatus as claimed in claim 5 in which the toe stabilizer is stepped for variable size feet.

7. Apparatus as claimed in claim 5 in which the toe stabilizes is reversible so that it can be used with both left and right feet.

8. Apparatus as claimed in claim 1 in which said ultrasonic transmitter includes means to amplify a pulse.

9. Apparatus as claimed in claim 1 including O-rings on said first and second hollow containers to allow the hollow container to slide in said main body.

10. Apparatus as claimed in claim 1 in which the ceramic transducers are mounted on a resilient end plate of said first and second bodies.

11. Apparatus as claimed in claim 10 in which said end plates are formed of a styrene based resilient adhesive.

12. Apparatus as claimed in claim 1 in which the means urging said transmitter into said recess comprise a

spring mounted in a third container, attached to first container.

13. Apparatus as claimed in claim 12 in which the spring abuts an end of said third container;

a piston to abut said spring to compress said spring;

means to fix the position of the piston and thus the tension of the spring.

14. Apparatus as claimed in claim 13 in which the piston is mounted on a rod that extends out of said third container and out of said main body;

a collar on said main body having first engagement means;

a second engagement means on said rod, engageable with said first engagement means whereby rotation of the rod acts to release and engage said first and second engagement means.

15. Apparatus to measure the physical characteristics of an object comprising a transmitting piezoelectric first transducer and a receiving piezoelectric second transducer to receive energy from the first transducer, said first transducer and second transducer being spaced apart to receive the object between them, the first and second transducers each being mounted on a resilient face plate by one face, whereby each of the transducers is able to resonate radially and axially upon receipt of an energy pulse.

16. Apparatus as claimed in claim 15 including means to apply voltage to the first transducer and means to measure the energy in the second transducer.

17. Apparatus as claimed in claim 15 in which the first and second transducers are each mounted within the tube having a face plate at its end.

18. Apparatus as claimed in claim 17 in which each face plate is molded to a predetermined shape to focus radiation.

19. Apparatus as claimed in claim 15 in which the resilient faceplate has the following characteristics:

(i) strong adhesion to the face of the ceramic and to the cylindrical main body;

(ii) acoustic impedance between that of a ceramic and human tissue;

(iii) inert to caustics, acids and oils;

(iv) mouldable; and

(v) electrically non-conductive.

20. Apparatus as claimed in claim 19 in which the resilient material is a styrene based polymer.

21. A method of measuring the physical characteristics of an object comprising subjecting the object to resonating frequencies from the same piezoelectric ultrasonic transmitter, a first resonating frequency obtained by resonating in the thickness mode and a second, lower resonating frequency, obtained by resonating in the radial mode.

22. A method as claimed in claim 21 that comprises determining the optimum high and low frequencies by finding a low frequency component having low attenuation on passage through the object and finding a high frequency component having high attenuation on passage through the object.

23. A method of spectral analysis of bone that comprises transmitting a sine wave burst through the bone, to eliminate errors due to the higher frequencies emitted by square wave radiation.

24. A method of measuring the energy transmitted through an object by a high frequency burst using both a radial and thickness mode resonance of a piezoelectric transducer transmitter and expressing the energy as a percentage of a total energy received that comprises:

(i) recording the voltage trace outputted by the receiver;

(ii) analyzing the trace by spectral analysis or difference trace;

(iii) deriving an expression:

$$\frac{[\text{area of high frequency component}]}{[\text{area of entire trace}]} \begin{matrix} \times 100 \\ - 100 \end{matrix}$$

said expression determining the percentage transmission to the higher frequency component without the need to use a reference.

25. A method of increasing transducer sensitivity in apparatus having receiving and emitting transducers that comprises using piezoelectric transducers that resonate at identical frequencies.

26. A method as claimed in claim 24 for deriving an index of structural integrity of bone by using the expression defined in claim 24, a high percentage indicating good structure and values below 80% indicating progressively poorer bone.

27. A method of measuring bone density using radial and thickness modes of resonance of a piezoelectric transducer transmitter without the use of a reference by eliminating error due to variability in the coupling medium, the method comprising:

(i) determining the minimum voltage of a low frequency burst displaying negligible attenuation on passage through the bone to achieve the amplitude to be used for future measurements by using a large number of measurements on a normal subject to find the minimal voltage, said minimal voltage being a normalizing factor (LFNF) used on all subsequent measurements of all subjects according to the relationship:

$$\text{Density} = \frac{\text{LFNF (voltage)}}{\text{low frequency (voltage)}} \times \frac{\text{High frequency (voltage)}}{\text{Heel width (mm)}}$$

$$= \frac{\text{voltage}}{\text{mm}}$$

(ii) the density expressed as volts/mm. being determined on a large number of young adults according to the expression:

$$\text{Density} = \frac{[\text{patient (volt/mm) x 100}]}{[\text{normal young adults (volts/mm)}]}$$

whereby density = a percentage of normal young adults.

28. A method of using radial and thickness modes of resonance of a piezoelectric transducer to eliminate error due to a coupling medium by transmitting a pulse of low frequency and negligible attenuation through the object to obtain a desired fixed voltage at a receiver;

repeating these measurements on the same individual over a long period using the same coupling throughout and recording the lowest voltage needed at the transmitter/transducer to achieve the fixed voltage;

using this frequency voltage as a low frequency normalizing factor (LFNF);

sending a low frequency burst followed by a high frequency burst;

expressing the LFNF as the numerator and the low frequency as the denominator to normalize the high frequency component.

29. A method of measuring the relative energy of a high frequency burst transmitted through an object that comprises recording the received energy using a piezoelectric ceramic transducer having two modes of operation, namely a thickness mode of operation and a radial mode of operation;

performing a spectral analysis of a trace of the received energy;

determining the area of the high frequency component;

comparing the area with that transmitted through a standard object of known characteristics, to show differences in composition or structure between the object and the standard.

30. A method as claimed in claim 29 in which the modulus of elasticity of the ceramic transducer is used to eliminate the need of external reference to measure the received energy.

31. A method of measuring the time of travel of a sound wave through an object using a highly undamped piezoelectric ceramic ultrasonic transducer and operating in radial and thickness modes, that comprises:

amplifying a trace of the sound wave;

measuring the time of first crossing of the base line of a trace of the received sound wave;

measuring a large number of similar objects to derive an average value and thus a constant time interval;

inserting this average value into a microprocessor for substraction from the time of the second crossing of the base line as determined by the microprocessor;

thereby obtaining an accurate, reliable time of travel of the sound wave through an object.

32. A method as claimed in claim 31 in which the time constant is determined at 668,400 Hz as 2.026 microseconds for the human heel bone.

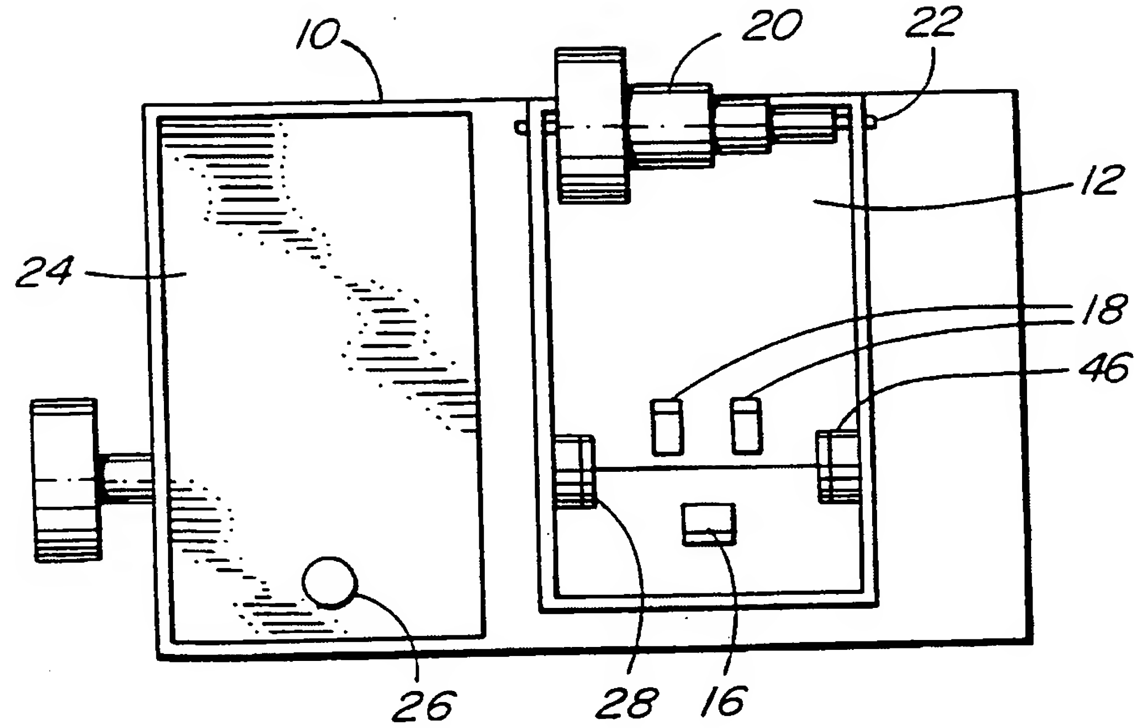

FIG. 1

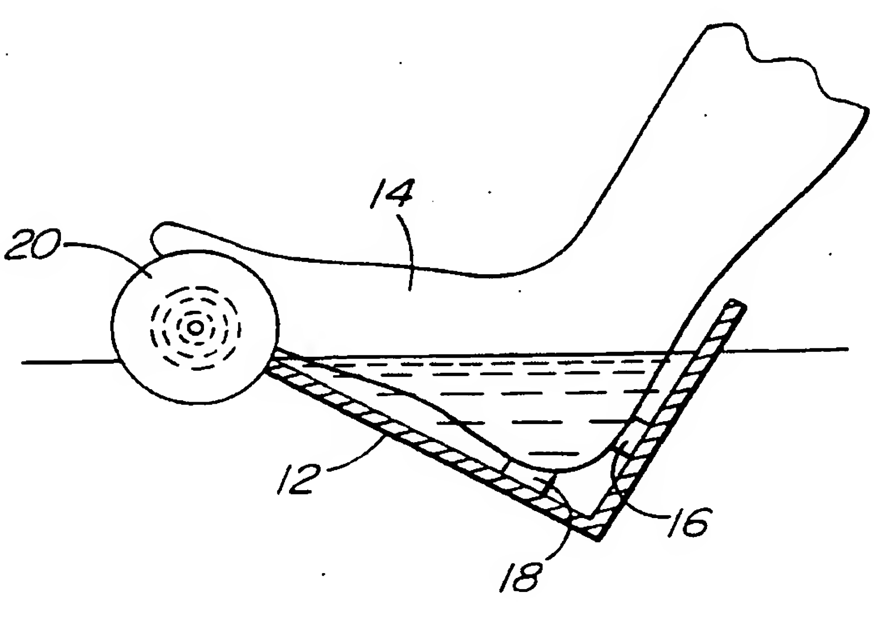

FIG. 1a

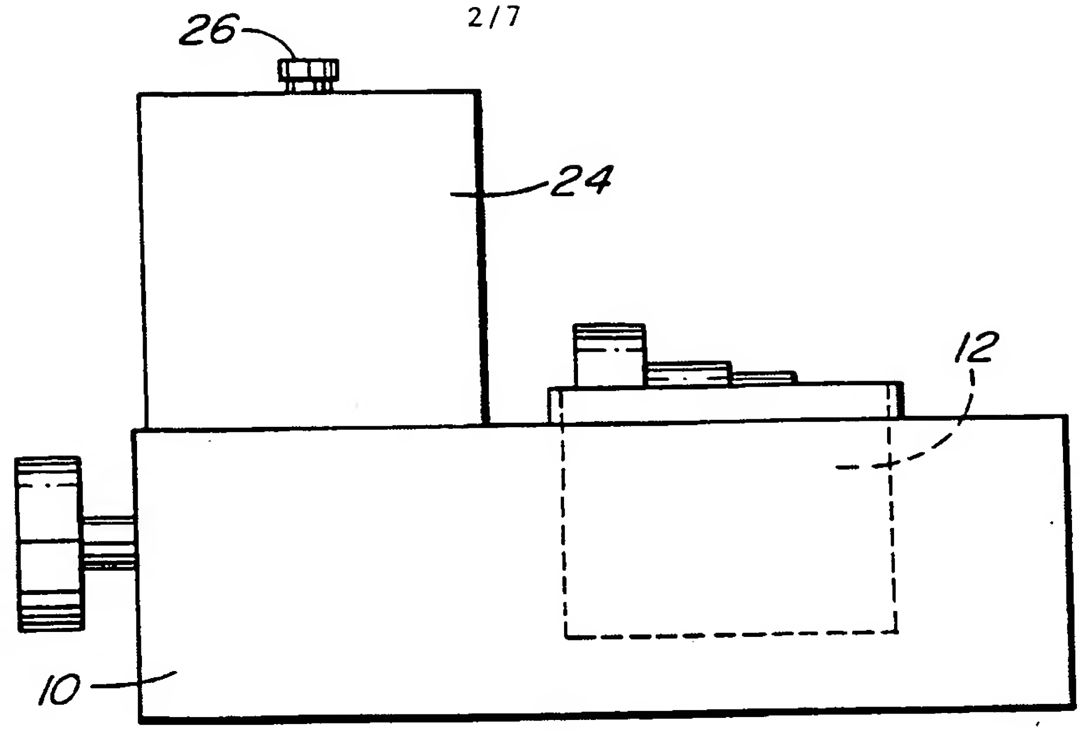

FIG. 2

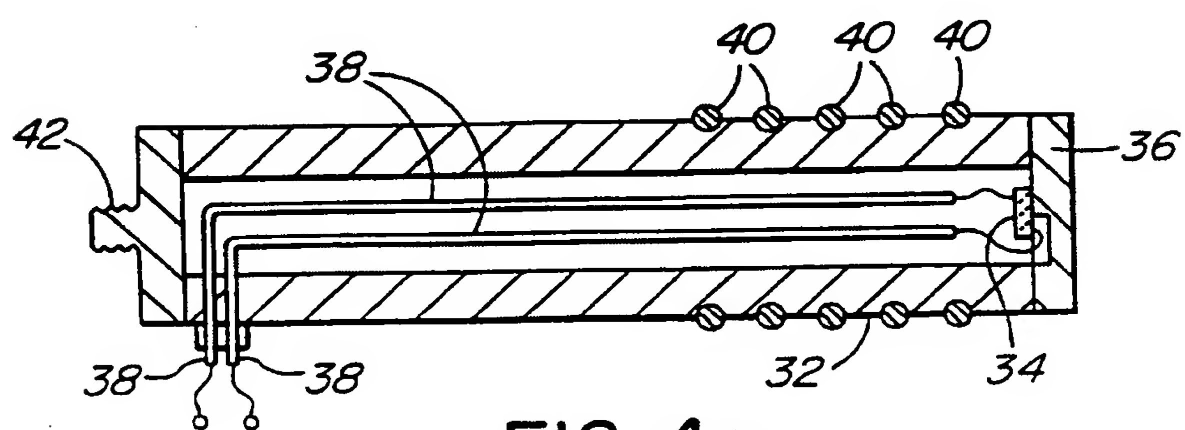

FIG. 4a

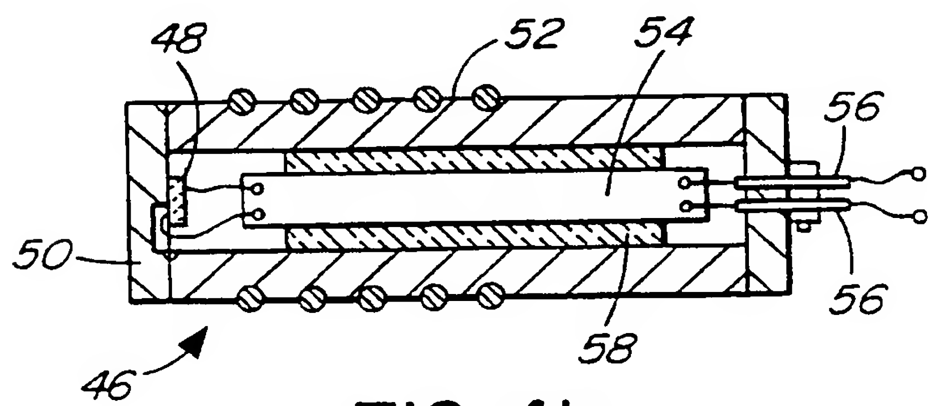

FIG. 4b

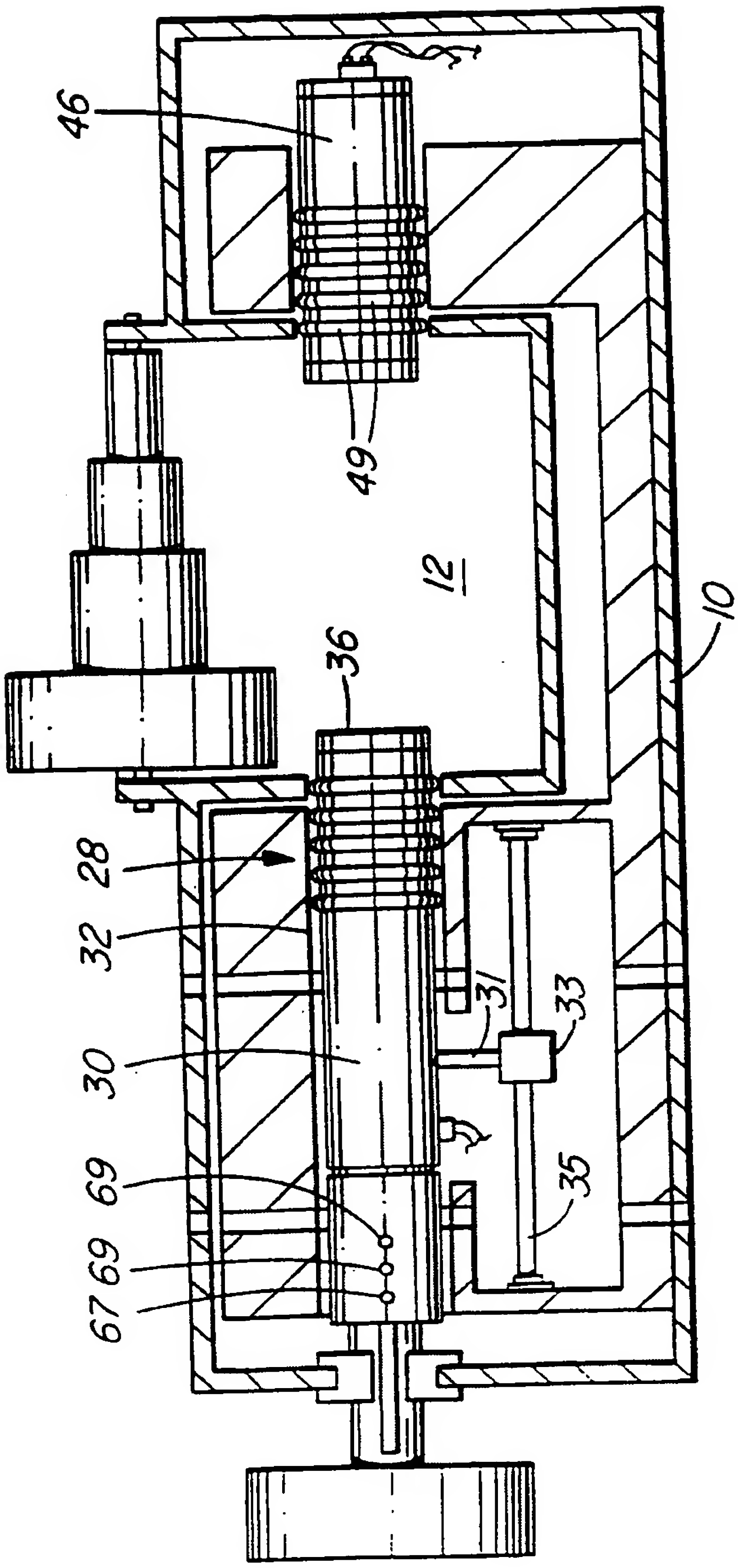

FIG. 3a

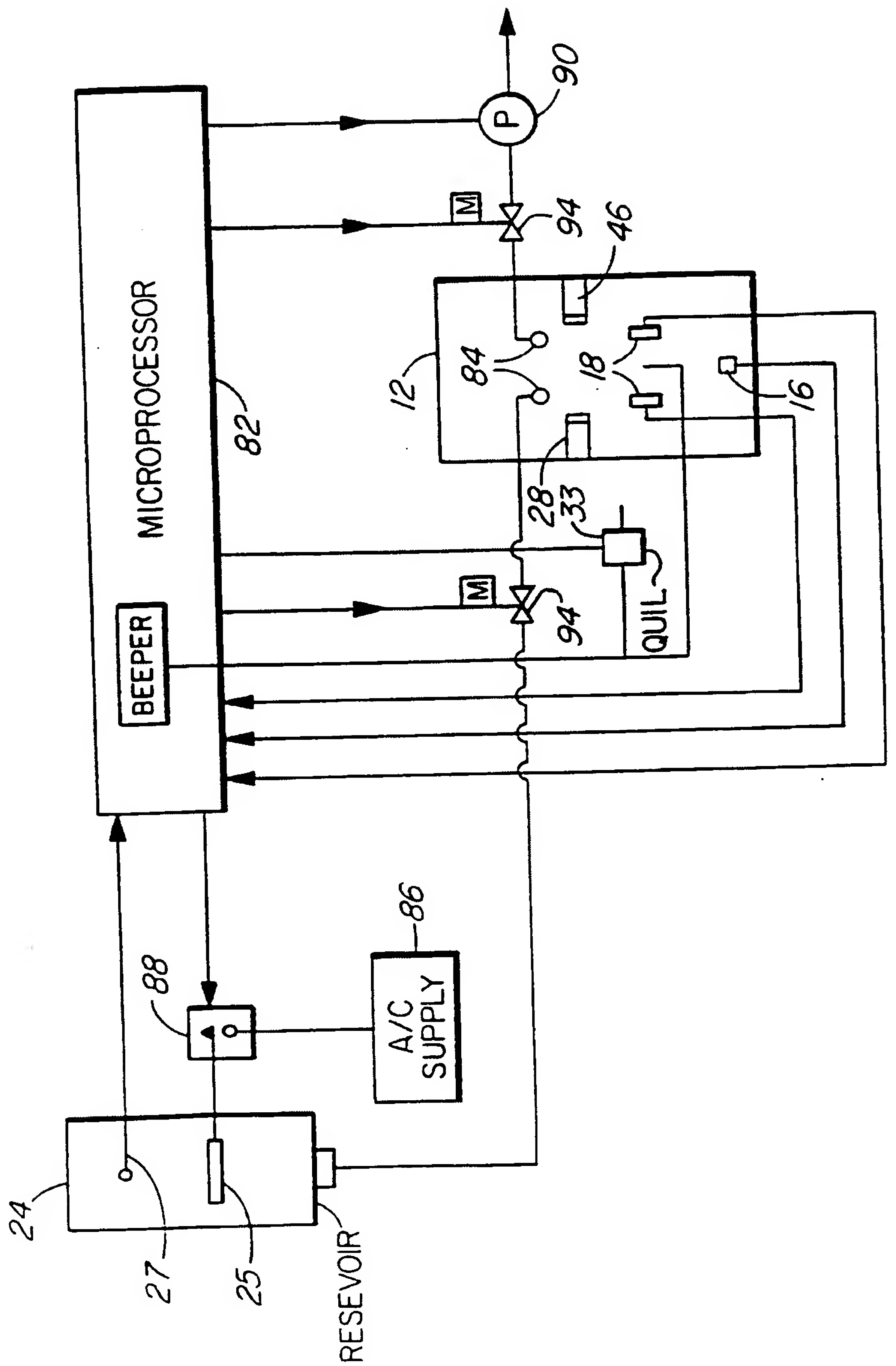
MICROPROCESSOR
82
BEEPER
P
90
M
94
46
12
84
18
16
28
33
QUIL
M
94
88
86
A/C SUPPLY
24
27
25
RESEVOIR

FIG. 5

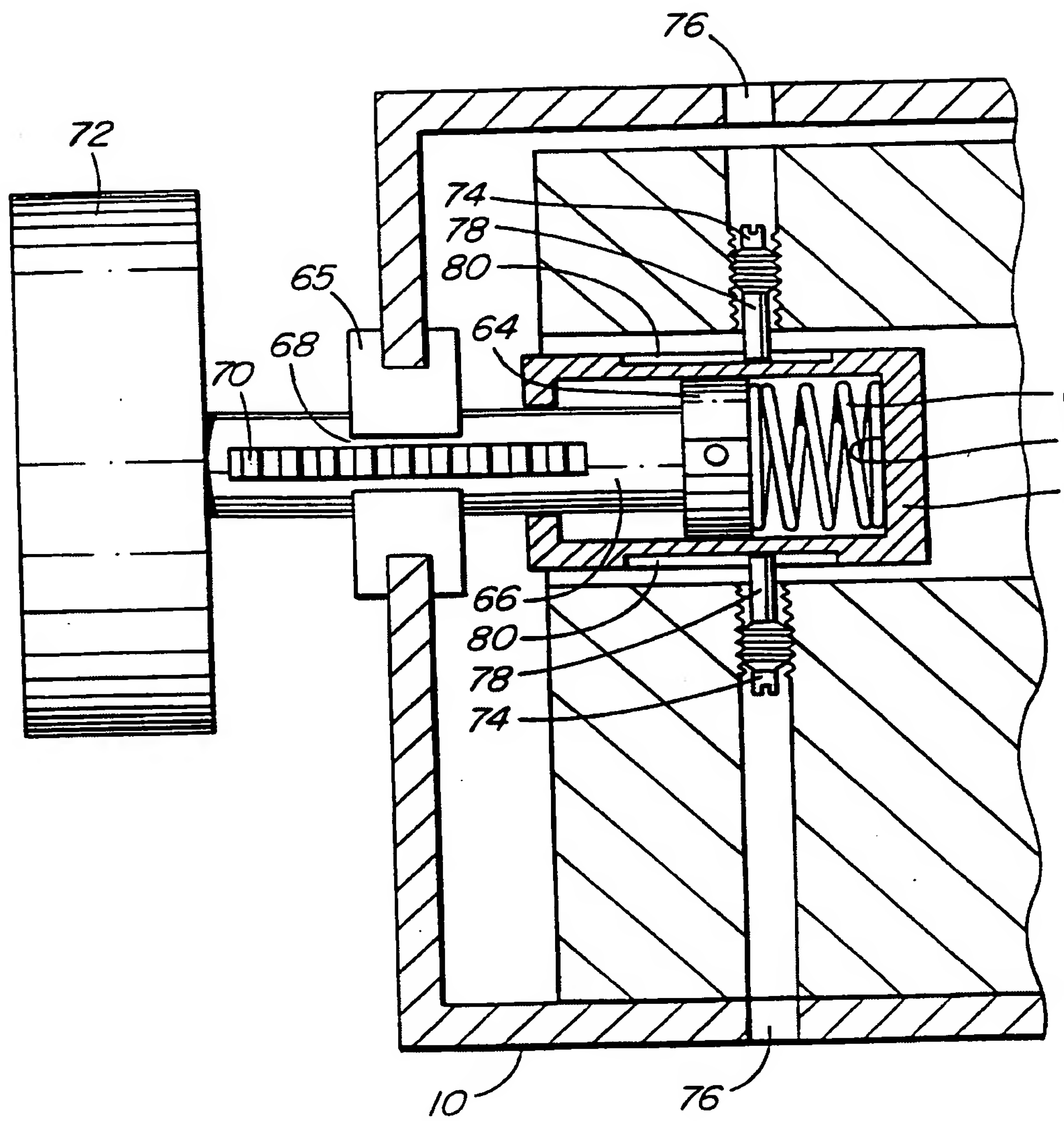

FIG. 3b

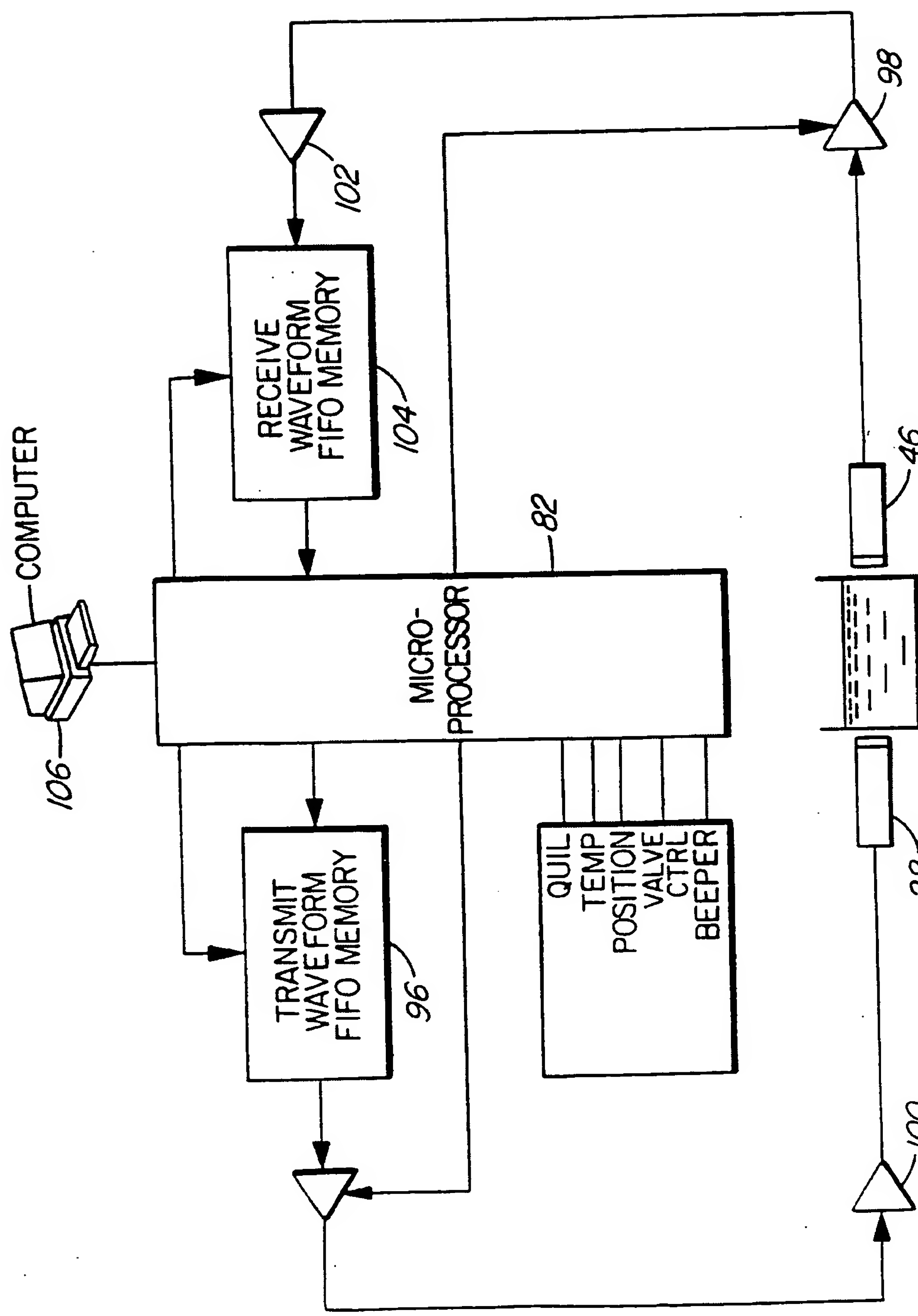
COMPUTER
106
RECEIVE WAVEFORM FIFO MEMORY
104
102
98
MICRO-PROCESSOR
82
TRANSMIT WAVEFORM FIFO MEMORY
96
QUIL TEMP POSITION VALVE CTRL BEEPER
46
14
28
100

FIG. 6

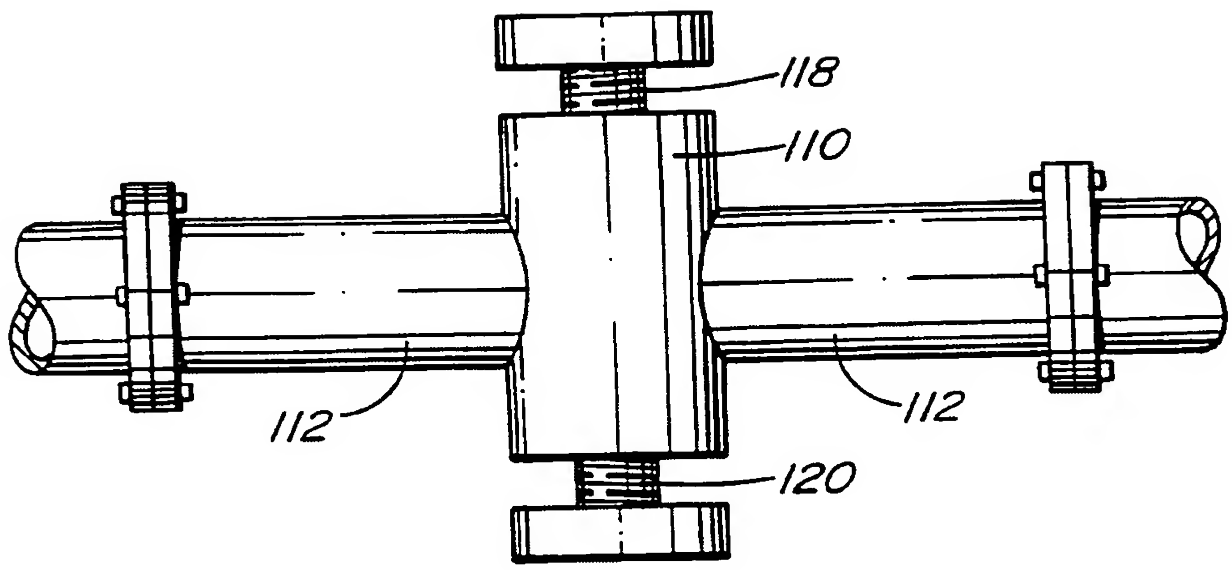

FIG. 7a

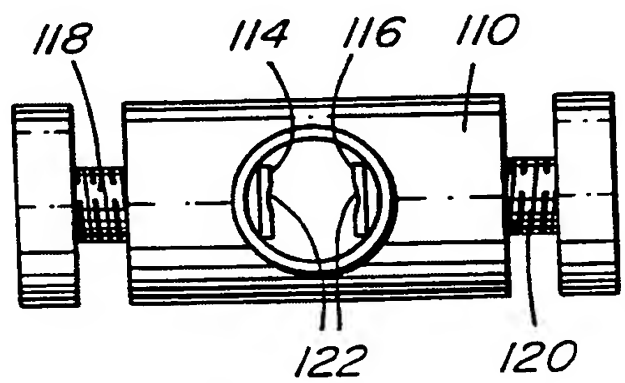

FIG. 7b

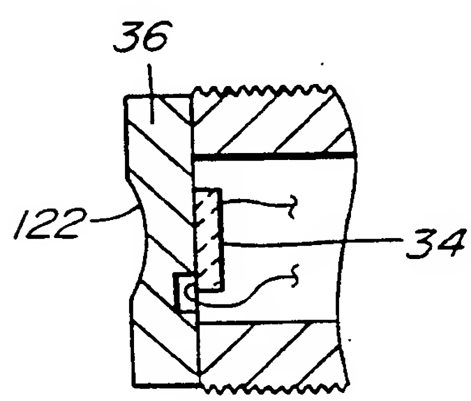

FIG. 7c

INTERNATIONAL SEARCH REPORT

International Application No
PCT/CA 99/00350

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B8/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 786 232 A (ALOKA CO., LTD.) 30 July 1997 (1997-07-30)	1,2,8,15
A	column 8, line 46 -column 10, line 31 column 20, line 7 -column 22, line 57	5,16-18
Y	US 5 003 965 A (R.J. TALISH ET AL.) 2 April 1991 (1991-04-02)	1,2,8,15
A	column 2, line 54 -column 3, line 68	9,10,14
A	column 4, line 41 - line 47	16,17, 21,29
A	EP 0 761 169 A (LILLY INDUSTRIES LTD.) 12 March 1997 (1997-03-12)	1-3,5
A	column 2, line 7 - line 40 column 3, line 34 - line 39	15-17,25

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 November 1999	06/12/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Rieb, K.D.

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INTERNATIONAL SEARCH REPORT

Inte 'onal Application No
PCT/CA 99/00350

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 335 661 A (J.N. KOBLANSKI) 9 August 1994 (1994-08-09) cited in the application	1,2,8, 10,15-18
A	column 3, line 25 -column 4, line 8	22
A	US 4 276 491 A (K.P. DANIEL) 30 June 1981 (1981-06-30) column 6, line 21 - line 50 column 7, line 7 -column 8, line 13	1,8,15, 18,21

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/CA 99/00350

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
EP 786232	A	30-07-1997	JP	9201355	A	05-08-1997
			JP	2923465	B	26-07-1999
			JP	9201356	A	05-08-1997
			JP	9201357	A	05-08-1997
			JP	9206299	A	12-08-1997
			US	5938610	A	17-08-1999
			US	5895357	A	20-04-1999
US 5003965	A	02-04-1991	CA	1328485	A	12-04-1994
			US	5186162	A	16-02-1993
			US	5211160	A	18-05-1993
EP 761169	A	12-03-1997	CA	2184028	A	01-03-1997
			JP	9103430	A	22-04-1997
			US	5704360	A	06-01-1998
US 5335661	A	09-08-1994	AU	6034694	A	14-09-1994
			WO	9418889	A	01-09-1994
US 4276491	A	30-06-1981	NONE			